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**UNITED STATES DISTRICT COURT**

**NORTHERN DISTRICT OF CALIFORNIA**

**OAKLAND**

| | |
|---|---|
| SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE,<br><br>Plaintiff,<br><br>vs.<br><br>ABBOTT LABORATORIES,<br><br>Defendant. | Case No. C 07-5702 CW<br><br>*Related per November 19, 2007 Order to Case No. C 04-1511 CW*<br><br>**NOTICE OF MOTION AND MOTION OF ABBOTT LABORATORIES TO DISMISS PLAINTIFF'S CLAIMS PURSUANT TO 12(b)(6)**<br><br>**Date: March 6, 2008**<br>**Time: 2:00 p.m.**<br>**Courtroom: 2 (4th Floor)**<br>**Judge: Hon. Claudia Wilken** |

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**NOTICE OF MOTION**

**TO PLAINTIFF AND ITS ATTORNEYS OF RECORD:**

PLEASE TAKE NOTICE THAT on March 6, 2008 at 2:00 p.m., or as soon thereafter as the matter may be heard in Courtroom 2, before the Honorable Claudia Wilken, in the United States District Court for the Northern District of California, Oakland Division, defendant Abbott Laboratories will move this Court pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure to dismiss the claims filed by Plaintiff SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") on November 7, 2007. This motion is supported by the accompanying Memorandum of Points and Authorities, all pleadings and documents on file with the Court, the confidential License Agreement dated December 13, 2002, that is repeatedly referenced in the pleadings, and such other argument or evidence as may be presented at the hearing on the motion.

## I. INTRODUCTION

This is one of several lawsuits concerning Norvir®, a patented drug used to "boost" the activity of protease inhibitors ("PIs") in the treatment of HIV. Abbott moves under Rule 12(b)(6) to dismiss all four counts of GSK's complaint because they fail to state a claim upon which relief can be granted.

In Counts 1, 3 and 4 of its complaint, GSK claims monopolistic conduct by Abbott in violation of the Sherman Act, the North Carolina Unfair Trade Practices Act and the North Carolina Prohibition on Monopolization Act, respectively. Like the plaintiffs in the related cases, GSK asserts that Abbott monopolized the purported market for boosted PIs by raising the price of Norvir (ritonovir alone) to make Abbott's Kaletra® (ritonovir plus lopinavir) comparatively less expensive than combining Norvir and competing PIs, including GSK's Lexiva.

The first problem with this claim is that it disregards the Ninth Circuit's recent decision in *Cascade Health Solutions v. PeaceHealth*, 502 F.3d 895 (9th Cir. 2007), which notes that "the Supreme Court has forcefully suggested that we should not condemn prices that are above some measure of incremental cost." *Id*. at 911. *Cascade* thus held that, "in the normal case, above-cost pricing will not be considered exclusionary conduct for antitrust purposes." *Id.* at 912. Pursuant to this Court's Case Management Order dated December 17, 2007, Abbott will file a separate

memorandum on January 31, 2008, fully addressing GSK's failure to allege below-cost pricing as part of a global motion to dismiss all of the new complaints under *Cascade*.

There are additional, independent reasons to dismiss GSK's three antitrust counts. Although GSK's allegations sound a familiar refrain, this complaint is materially different from the earlier Doe and SEIU Norvir complaints this Court declined to dismiss. Obviously, no Sherman Act claim can survive if the complaint fails to allege conduct *outside* the scope of Abbott's patents. For the Doe and SEIU complaints, this Court declined at that "early juncture" to find that Abbott's patents cover the so-called "Boosted Market" of PIs boosted by Norvir.

Here, in contrast, GSK affirmatively alleges—repeatedly—that Abbott's patents, or "intellectual property," *do* cover the sale of "PIs for administration with Norvir." (*See, e.g.*, Compl. ¶¶ 17, 20, 21, 36). GSK also repeatedly references the parties' license agreement, which likewise confirms that Abbott's patents "relat[e] to the use of Ritonavir and pharmaceutical formulations thereof *in combination with other protease inhibitors*." (Declaration of Nicole M. Norris, ¶ 2, Exhibit A, License Agreement ¶ 1.12 (emphasis added) ("Ex. A.")). These allegations must be accepted as true under Rule 12(b)(6) and, thus, GSK has pleaded facts disproving its own claim. A patent owner cannot "unlawfully" monopolize a market covered by its patent.

The complaint's reference to Abbott's patents also warrants dismissal because GSK has directly implicated federal patent law and, thus, the Federal Circuit has jurisdiction over this case. Federal Circuit jurisdiction exists where, as here, "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law." *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 830 (2002). That is true here. By recognizing the existence of patents over the market Abbott allegedly monopolized "unlawfully," GSK's complaint establishes that its right to relief "necessarily depends on resolution of a substantial question of federal patent law"—*i.e.*, the scope of Abbott's patent protection. Thus, Federal Circuit law controls and, as this Court is aware, the Federal Circuit has already rejected GSK's patent-monopoly leveraging theory.

For yet another reason, that Federal Circuit decision (as later confirmed by the Seventh Circuit in a scholarly opinion by Judge Easterbrook) defeats GSK's antitrust claims under the North Carolina statutes (Counts 3 and 4). For those claims, which are based largely on the same patent-

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monopoly leveraging theory, this Court must decide whether the North Carolina courts would follow the approach taken by the Ninth Circuit (which accepted GSK's purported patent-monopoly leveraging theory) or the approach taken by the Federal Circuit and the Seventh Circuit (which soundly rejected that theory). The reality is that North Carolina would certainly follow the Federal Circuit and Seventh Circuit decisions, which explain in great detail why the earlier Ninth Circuit decision is contrary to settled patent and antitrust law. This is especially true given that a North Carolina district court already refused to recognize "monopoly leveraging" as a viable antitrust theory, and no North Carolina court or federal court in the Fourth Circuit has reached the opposite conclusion.

The remaining count (Count 2) alleges a breach of the implied covenant of good faith and fair dealing relating to the parties' patent license agreement. This count is legally defective. Abbott's sole contractual obligation was to permit GSK to promote and market its PIs in combination with Norvir, something GSK readily alleges it has done and is doing. Accordingly, GSK has not sued for breach of contract.

Instead, it asks this Court to read an *implicit* promise into the parties' agreement that Abbott would limit its "future increases in the price of Norvir" to levels "consistent with past increases." (Compl. ¶ 64). No such promise—which would have been an illegal price-fixing agreement in violation of the Sherman Act—appears anywhere in the parties' license agreement. On the contrary, the agreement's plain language refutes any such agreement. The parties expressly disclaimed *all* warranties not explicitly contained in the agreement and included an integration clause canceling all prior agreements and understandings. Governing law uniformly rejects GSK's effort to bring a nonviable contract claim under an implied covenant theory and, in particular, its effort to read new and conflicting obligations into the parties' contract. This claim, like GSK's antitrust claims, should be dismissed.

## II. BACKGROUND

### A. The Alleged Relevant Markets

As this Court knows, PIs are powerful drugs used to stop HIV's replication. (*Id.* ¶ 13). There are many PIs on the market, including two sold by Abbott and one sold by GSK. (*Id.* ¶¶ 13,

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19). Norvir® is a PI typically used to "'boost' the effects of a PI paired with it." (*Id.* ¶ 15). Abbott also sells Kaletra®, which combines Abbott's "PI (lopinavir) and Norvir (ritonavir) in a single pill." (*Id.* at ¶ 19).

GSK alleges that there are two relevant markets: the "market for PI boosters" and the "market for boosted PIs." (*Id.* ¶ 38). The "market for PI boosters"—referred to as the Booster Market—consists of the market for Norvir when used to boost the effects of PIs. (*Id.* at ¶ 39). GSK alleges that Abbott "has a 100 percent share of the market for PI boosters," (*id.*), and "is the sole manufacturer of Norvir." (*Id.* ¶ 23). But GSK does not allege that Abbott has "unlawfully" monopolized the Booster Market. This is because, as the Court is aware, the parties in other Norvir cases have not disputed that Abbott's monopoly in that market is perfectly legal under the patent laws. (*See* 10/21/04 Order at 5).

GSK focuses instead on Abbott's conduct in the "market for boosted PIs"—referred to as the Boosted Market. (*Id.* ¶ 40). GSK freely admits that Abbott and GSK, "among others, compete within the market for boosted PIs by developing, marketing and selling boosted PIs." (*Id.* ¶¶ 5-6, 40). At the same time, however, GSK alleges that Abbott has unlawfully monopolized that very same market. (*Id.* ¶¶ 54-62).

### B. GSK Admits In Its License Agreement With Abbott That Abbott's Patents Cover The Combination Of Norvir And PIs In The Boosted Market

Far from excluding GSK from the Boosted Market—which Abbott had every legal right to do by virtue of its booster patents—Abbott expressly agreed to allow GSK into the market in exchange for a royalty, which is a completely appropriate use of a patent.

In a December 2002 Non-Exclusive License Agreement, GSK agreed to license Abbott's "intellectual property" concerning Norvir. (*Id.* ¶¶ 17, 20). GSK repeatedly references the License Agreement in its complaint (*see id.* ¶¶ 2, 3, 20, 21, 23, 35, 36, 37, 43, 50, 64, 65, 72, 76), and even bases one of its claims on that agreement. (*Id.* ¶¶ 63-66).

Although GSK did not attach the agreement to its complaint, the Court should consider the referenced License Agreement when deciding whether the complaint states a claim. "[T]he incorporation by reference doctrine . . . permits a district court to consider documents 'whose

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contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the [plaintiff's] pleading.'" *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 986 (9th Cir. 1999) (citation omitted) (alteration in original).

The License Agreement signed by GSK is replete with admissions that Abbott's patents cover the use of Norvir in combination with PIs. It states that "Abbott owns certain patents related to the use, marketing and promotion of Ritonavir (as defined below), its protease inhibiting compound (marketed under the trade name Norvir®), *in combination with other products indicated for the treatment of HIV*." (Ex. A, License Agreement at 1 (emphasis added)). In recognition of these patent rights, GSK agreed to pay a royalty for a license to promote and market certain of its PIs, including Lexiva, with Norvir. The License Agreement expressly defines the term "Licensed Patents" to mean all patents set forth on Schedule II of the agreement "relating to the use of Ritonavir and pharmaceutical formulations thereof *in combination with other protease inhibitors*." (*Id*. ¶ 1.12 (emphasis added)). Schedule II, in turn, lists U.S. Patent No. 5,886,036 ("the '036 patent") as a patent that covers "Combination of Pharmaceutical Agents for Treatment of HIV Infection Comprising Ritonavir and a Second HIV Protease Inhibitor." (*Id*. at p. 20). Also listed are U.S. Patent No. 6,037,157 ("the '157 patent") and the patent application (no. 9/957,171) that resulted in U.S. Patent No. 6,703,403 ("the '403 patent"), which cover "Pharmacokinetic Enhancement with Ritonavir." (*Id*.).

Abbott's sole obligation under the License Agreement appears in paragraph 2.1, which discusses the scope of the license granted to GSK. Abbott had a choice before entering into this agreement. It could have precluded *any* party, including GSK, from selling a PI for use in combination with Norvir. But it chose instead to enforce its patents by licensing them in return for a royalty. (Compl. ¶¶ 20-22, 43). GSK thus received the right to promote its drug in combination with Norvir, which it has done to the tune of tens of millions of dollars every year.

Contrary to GSK's allegation, the License Agreement imposed no other obligation on Abbott, and it certainly did not impose an obligations relating to Norvir's price in the marketplace. Abbott simply did not "agree" on price with a competitor in violation of the Sherman Act's prohibition against any such price fixing agreements. "Price-fixing agreements between two or more

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competitors, otherwise known as horizontal price-fixing agreements, fall into the category of arrangements that are *per se* unlawful." *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006); *see* 15 U.S.C.A. § 1. Nor did Abbott make any assurances to GSK concerning its expected profits under the License Agreement. Moreover, the License Agreement expressly disclaims all "express or implied" warranties as well as "[a]ll express or implied agreements and understandings, either oral or written" not incorporated into the agreement. (Ex. A, License Agreement ¶¶ 5.4, 11.5).

**C. GSK's Patent-Monopoly Leveraging Theory**

In its complaint, GSK objects to Abbott's December 2003 price increase on Norvir (but GSK fails to mention that it raised the price of its own PI *five times* since its launch). Specifically, GSK alleges that about one year after execution of the GSK License Agreement, Abbott raised Norvir's price from $1.71 to $8.57 at its most common daily dose of 100 milligrams. (As an aside, GSK charges $40.80 for its recommended non-boosted dose of Lexiva).

GSK now accuses Abbott of improperly "rais[ing] the price of Norvir when co-prescribed with its competitors' boosted PIs, like Lexiva, while keeping the price of Norvir low when used in Abbott's own boosted PI, Kaletra." (Compl. ¶ 45). GSK blames the Norvir price increase for its own drug's allegedly poor performance in the Boosted Market. (*Id.* ¶¶ 46-47). This conduct, according to GSK, violated the Sherman Act as well as North Carolina's unfair trade practices and anti-monopoly statutes and harmed GSK in the Boosted Market. (*Id.* ¶¶ 45-46).

GSK also alleges that Abbott's purported monopolistic conduct breached an implied agreement to keep "future increases in the price of Norvir" at a level "consistent with past increases." (*Id.* ¶ 64). But GSK does not allege that Abbott's pricing of Norvir actually breached any provision of the License Agreement.

## III. STANDARD OF REVIEW

Abbott moves to dismiss all four counts in the complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Rule 12(b)(6) "tests the legal sufficiency of the claims alleged in the complaint." *Falk v. Gen. Motors Corp.*, 496 F. Supp. 2d 1088, 1093 (N.D. Cal. 2007). "'[A] plaintiffs' obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.'" *Id.*

(quoting *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1964-65 (2007)). To survive a motion to dismiss, a plaintiff must allege facts sufficient to demonstrate "plausible entitlement to relief." *Bell Atl. Corp.*, 127 S. Ct. at 1965; *In re Graphics Processing Units Antitrust Litig.*, No. C 06-07417 WHA, 2007 WL 2875686, at *8 (N.D. Cal. Sept. 27, 2007) (quoting *Twombly*, 127 S. Ct. at 1964-65). A "bare assertion" of a violation of the law will not suffice. *Twombly*, 127 S. Ct. at 1966.

## IV. ARGUMENT

GSK's complaint should be dismissed. As demonstrated below, it fails to allege facts sufficient to demonstrate a plausible entitlement to relief under the Sherman Act, the implied covenant of good faith and fair dealing, the North Carolina Unfair Trade Practices Act, or the North Carolina Prohibition on Monopolization Act.

### A. GSK Has Failed To State A Claim Under The Sherman Act

Count 1 of the complaint fails to state a claim under the Sherman Act, which makes it unlawful to "monopolize any part of the trade or commerce among the several states." 15 U.S.C. § 2. To prevail on a Section 2 monopolization claim, GSK must plead and prove that Abbott: "(1) possessed monopoly power in the relevant market, (2) willfully acquired or maintained that power through exclusionary conduct, and (3) caused antitrust injury." *MetroNet Servs. Corp. v. Quest Corp.*, 383 F.3d 1124, 1130 (9th Cir. 2004).

GSK's own complaint shows that it cannot satisfy this burden as a matter of law for two independent reasons. First, GSK alleges that Abbott's patent protection covers not only the Booster Market, but the Boosted Market as well, thus falling squarely within the antitrust immunity afforded by the patent laws. Second, even if the Court were to read GSK's complaint as alleging that Abbott's patent protection covered only the Booster Market, and not the Boost*ed* Market, controlling Federal Circuit precedent establishes that such patent protection immunizes Abbott from antitrust liability.

#### 1. GSK's Allegations That Abbott's Patents Cover The Use Of Norvir In Combination With Other PIs Bar Its Sherman Act Claim

As this Court previously recognized, antitrust laws are implicated only when a patent owner "extends its monopoly beyond the scope of the patent." (10/21/04 Order at 4). That is because a

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patentee cannot "unlawfully" monopolize a market covered by a patent. As the Supreme Court explained, "[a] patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly." *Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964). The Federal Circuit similarly noted that "'[t]he owner of a patented article can, of course, charge such price as he may choose.'" *Monsanto Co. v. McFarling*, 302 F.3d 1291, 1299 (Fed. Cir. 2002) (citation omitted). And, as the Ninth Circuit put it: "[S]etting high prices in the original 'monopoly' market" is among the "ways that a monopolist can permissibly benefit from its position." *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 548 (9th Cir. 1991); *see also Atari Games Corp. v. Nintendo of Am. Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990) (holding that antitrust laws are implicated only when the patent owner extends its monopoly power "beyond the limits of what Congress intended to give in the patent laws").

Under this precedent, GSK has pleaded itself out of court. "Of course a plaintiff can plead himself out of court. . . . If he alleges facts that show he isn't entitled to a judgment, he's out of luck." *Early v. Bankers Life and Cas. Co.*, 959 F.2d 75, 79 (7th Cir. 1992); *see also Stidham v. Jackson*, No. 2:07cv00028, 2007 WL 2156155, at *5 (W.D. Va. July 26, 2007) (granting the defendant's motion to dismiss based on the content of the complaint and the plaintiff's admissions); *Hann v. Michigan*, No. 05-CV-71347, 2007 WL 1565465, at *2 (E.D. Mich. May 29, 2007) (holding that "Plaintiff's admissions in his Complaint that he did not file the proper grievances can support a defendant's Rule(b)(6) motion to dismiss"); *SAI Indus. Corp. v. U.S.*, 63 Fed. Cl. 1, 4 n.8 (Fed. Cl. 2004) (stating that the court would be justified to dismiss plaintiff's argument based on "plaintiff's contrary admissions"); *Complaint of Martin*, 18 F. Supp. 2d 126, 129 (D. Mass. 1998) (dismissing the plaintiff's petition based on the plaintiff's admissions).

GSK pleaded itself out of court by alleging that Abbott owns patents over the very market it allegedly has monopolized. Abbott recognizes that this Court previously denied a motion to dismiss SEIU's complaint on the ground that the Court was "not willing, at [that] early juncture in the litigation, to rule that Defendant can patent a procedure in which HIV patients take a drug manufactured and sold by a third party along with Defendant's own." (*See* 3/02/05 Order at 7).

But this case is different. Unlike in the SEIU case, GSK's complaint establishes that

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Abbott's patent protection reaches this very procedure. In its complaint, GSK repeatedly acknowledges that Abbott has patents covering "*PIs for administration with Norvir*." (*See, e.g.*, Compl. ¶¶ 17, 20, 21, 36) (emphasis added)). Specifically, GSK alleges that "Abbott never sought to use its *intellectual property* to prevent others from selling PIs for administration with Norvir. Instead, it chose to profit by *licensing competitors the right to market PIs to be co-administered with Norvir*." (*Id*. at ¶ 17 (emphasis added)). Similarly, GSK alleges that it "acquiesced" to Abbott's "demand" that a license from Abbott is required "to promote [GSK's] existing PIs, as well as PIs it had under development, with Norvir." (*Id*. at ¶ 20).

The complaint further alleges that "Abbott gave GSK the right to promote the use and administration of its PIs with Norvir" through a license agreement and that, in fact, "GSK paid substantial sums of money" to Abbott for that right. (*Id*. at ¶ 21). Elsewhere, the complaint acknowledges that GSK was "able to promote the co-prescription and co-administration of its PI products with Norvir . . . by virtue of the license for which it had paid." (*Id*. at ¶ 36). According to the complaint, third parties held a similar view that Abbott's patent rights covered the administration of Norvir with PIs: "GSK is informed and believes . . . that other pharmaceutical companies, including BMS, took similar licenses allowing the promotion of their PIs with Norvir during the same timeframe." (*Id*. at ¶ 22).

In the License Agreement itself, which is referenced throughout the complaint, GSK concedes that Abbott's patents cover "the use of [Norvir] in combination with other protease inhibitors"—the very definition of the Boosted Market. (Ex. A, License Agreement ¶ 1.12). In fact, the purpose of the License Agreement was to address the fact that "Abbott owns certain patents related to the use, marketing and promotion of [Norvir] in combination with other products indicated for the treatment of HIV." (*Id.* at 1). The agreement specifically references at least two such patents—the '036 and '157 patents, both of which concern the combination of Norvir with PIs—and further references the patent application (no. 9/957,171) that resulted in the '403 patent. (*Id*. at 20).

Nowhere in the complaint does GSK retreat from its repeated allegations and admissions in the License Agreement that Abbott's patents cover the Boosted Market. Nor does GSK allege that these patents should be declared invalid, or otherwise unenforceable. In any event, subsequent

invalidation of Abbott's patents would be irrelevant to GSK's antitrust claims. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1309 (11th Cir. 2003) ("To the extent that the appellees have demonstrated nothing more than subsequent invalidity, we hold that this alone is insufficient to render the patent's potential exclusionary effects irrelevant to the antitrust analysis.").

GSK's allegations and admissions in the License Agreement that Abbott's patents cover the Boosted Market distinguish this case from the related cases and, more importantly, establish Abbott's antitrust immunity to GSK's Sherman Act claim. Count 1 thus should be dismissed because GSK has no "plausible entitlement to relief." *Twombly*, 127 S. Ct. at 1967; *see also SMC Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) (in affirming dismissal of Sherman Act claim, court held that "where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws").

**2. The Scope Of Abbott's Patent Protection Under The Patent Laws Is Governed By Federal Circuit Precedent, Which Has Rejected GSK's Patent-Monopoly Leveraging Theory**

This Court should dismiss the Sherman Act claim on the independent ground that the Federal Circuit has jurisdiction over any appeal in this case, and binding Federal Circuit precedent has rejected GSK's patent-monopoly leveraging theory of antitrust liability.

Based on the patent-specific allegations in GSK's complaint—allegations confirmed by the License Agreement—the Federal Circuit, not the Ninth Circuit, will resolve any appeal in this case. In 28 U.S.C. § 1295(a)(1), Congress granted the Federal Circuit exclusive jurisdiction over "an appeal from the final decision of a district court of the United States . . . if the jurisdiction of that court was based, in whole or in part, on [28 U.S.C.] section 1338." Section 1338, in turn, provides in relevant part that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents."

The term "arising under" the patent laws does not, as the Supreme Court has confirmed, limit Federal Circuit jurisdiction to patent infringement cases. *Holmes Group, Inc.*, 535 U.S. at 830. Rather, a claim "arises under" the patent laws if either "'federal patent law creates the cause of action ***or*** . . . the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law.'" *Id.* (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809

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(1988)) (emphasis added). In other words, even if the claim is based on a non-patent statute, the Federal Circuit still has jurisdiction if the complaint demonstrates that the claim requires resolution of a substantial question of patent law. *See Franchise Tax Bd. v. Laborers Vacation Trust*, 463 U.S. 1, 10-11 n.9 (1982) (discussing the standard under the well-pleaded complaint rule, which was adopted for Federal Circuit jurisdiction in *Holmes*).

As the Ninth Circuit had explained, even a single claim that meets this broad definition of "arises under"—"no matter how worthy or unworthy and no matter how significant to the litigation—operates as an 'on switch' or automatic trigger for Federal Circuit jurisdiction." *Breed v. Hughes Aircraft Co.*, 253 F.3d 1173, 1178 (9th Cir. 2001) (transferring case to Federal Circuit). Moreover, even the lack of any "reference to federal patent law . . . does not necessarily mean the claim does not 'arise under' patent law. Just as a plaintiff may not defeat removal by omitting to plead necessary federal questions in a complaint, . . . so a plaintiff may not defeat § 1338(a) jurisdiction by omitting to plead necessary federal patent-law questions." *Christianson*, 486 U.S. at 809 n.3 (quotation omitted). For example, the Ninth Circuit transferred a case to the Federal Circuit because even though plaintiffs "structured their arguments in terms" of compliance with the Administrative Procedure Act and its rule-making procedures, the case "turn[ed] on a construction of patent law." *Animal Legal Def. Fund v. Quigg*, 900 F.2d 195, 196 (9th Cir. 1990).

Under this settled law, the Federal Circuit has jurisdiction over this case because GSK's allegations necessarily depend on resolution of a substantial question of federal patent law—*i.e.*, the scope of Abbott's patent protection. *See Holmes*, 535 U.S. at 829-30. Although Federal Circuit jurisdiction cannot be based on defenses, the scope of Abbott's patent protection in the context of this case is not a defense but, rather, an element of GSK's claim for relief.

As discussed above, the second element of a Sherman Act claim requires GSK to plead and prove that Abbott willfully acquired or maintained monopoly power through "exclusionary conduct." Under both Federal Circuit and Ninth Circuit law, resolution of that element of the claim "necessarily" requires the resolution of patent issues. In *Image Technical Servs. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997), the Ninth Circuit held that in the context of a patent-monopoly leveraging theory, "conduct permissible under the patent laws" is not "exclusionary conduct" for

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purposes of Sherman Act liability. *Id.* at 1216 (quotation omitted). It noted, however, that the "right of exclusion [does not] protect an attempt to extend a lawful monopoly *beyond* the grant of a patent" and, thus, "*[m]uch depends* . . . on the definition of the patent grant and the relevant market." *Id.* at 1216 (emphasis added). As a result, the Court held that resolution of a patent-leveraging claim "***requires*** that some weight be given to the intellectual property rights of the monopolist." *Id*. at 217 (emphasis added); *see also id.* at 1219 (holding that "desire to profit from . . . intellectual property rights" carries a legal presumption of being "legitimately procompetitive").

To state a claim under *Image Technical*, therefore, GSK must establish exclusionary conduct by Abbott beyond its antitrust immunity afforded by the patent laws. Accordingly, GSK's complaint—again, to the extent GSK has not pleaded itself out of court—necessarily depends on resolution of a substantial question of federal patent law concerning the scope of Abbott's patent protection. *See, e.g., Netflix, Inc. v. Blockbuster, Inc.*, 477 F. Supp. 2d 1063, 1066 (N.D. Cal. 2007) (applying Federal Circuit law to claim construction issues). As a result, the Federal Circuit will have exclusive appellate jurisdiction. *See Holmes*, 535 U.S. at 830.

This question of appellate jurisdiction is important because the Federal Circuit applies its "own law, not regional circuit law, to resolve issues that clearly involve [its] exclusive jurisdiction." *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1067 (Fed. Cir. 1998). In particular, the Federal Circuit applies its own laws to determining "whether or not the patentee enjoys antitrust immunity under the patent laws" based on the patent grant because any other result would "risk disturbing 'Congress's goal of ensuring patent-law uniformity.'" *Unitherm Food Sys. v. Swifth-Eckrich, Inc.*, 375 F.3d 1341, 1355 n.3 (Fed. Cir. 2004) (vacated on other grounds) (quoting *Nobelpharma*, 141 F.3d at 1067-68); *see also Image Technical Servs.*, 125 F.3d at 1216-17 ("The relevant market for determining the patent . . . grant is determined under patent . . . law.").

As the Court is aware, the Federal Circuit has already rejected the patent monopoly leveraging theory that GSK has unsuccessfully attempted to plead in this case. In *In re Independent Service Orgs. Antitrust Litig.*, 203 F.3d 1322 (Fed. Cir. 2000), the Federal Circuit specifically held that a "patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws" and, in fact, "a patent may confer

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the right to exclude competition altogether in more than one antitrust market." *Id.* at 1327. In so holding, the court expressly "declined to follow" the Ninth Circuit's decision in *Image Technical Servs. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997), which adopted a rebuttable presumption that the exercise of the statutory right to exclude provides a valid business justification for consumer harm. *In re Indep. Servs. Org. Litig.*, 203 F.3d at 1328.

In sum, binding Federal Circuit precedent cloaks Abbott's Norvir pricing decisions with immunity from Sherman Act liability. Count 1 should be dismissed on this ground as well.

**B. GSK Has Failed To State A Claim For Breach Of The Implied Covenant Of Good Faith And Fair Dealing**

Count 2 for breach of the implied covenant of good faith and fair dealing also fails to state a claim. GSK has not alleged that Abbott breached any provision in the License Agreement. Nor could it do so. "[A] patent license agreement is in essence nothing more than a promise by the licensor not to sue the licensee." *Spindelfabrik Suessen-Schurr Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaf*, 829 F.2d 1075, 1081 (Fed. Cir. 1987). Thus, Abbott's only obligation was to permit GSK to promote and market its PIs in administration with Norvir without fear of a lawsuit—something GSK readily admits it has been allowed to do. (*See* Compl. ¶ 40). Instead, GSK seeks to impose a new obligation on Abbott based on GSK's purported "reasonable expectation" that Abbott would limit "future increases in the price of Norvir" to a level "consistent with past increases." (*Id*. at ¶ 64).

This claim fails under New York law, which governs in light of the choice of law provision in the License Agreement. (*See* Ex. A, License Agreement ¶ 11.4). All contracts subject to New York law include an implied covenant of good faith and fair dealing that governs contract performance. *Dalton v. Educ. Testing Serv.*, 87 N.Y.2d 384, 389 (1995). But, as the New York Court of Appeals (the highest court in the State) emphasized: "The duty of good faith and fair dealing . . . is not without limits, *and no obligation can be implied that 'would be inconsistent with other terms of the contractual relationship.'*" *Id.* (emphasis added) (citation omitted). As demonstrated below, Count 2 far exceeds these limits and, therefore, should be dismissed.

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**1. GSK Cannot Bring An Implied Covenant Of Good Faith And Fair Dealing Claim As A Substitute For Its Nonviable Contract Claim**

Count 2 should be summarily dismissed because, in general, "New York does not recognize a separate cause of action for violation of the implied covenant of good faith and fair dealing." *Cohen v. Nassau Educators Fed. Credit Union*, No. 15094-05, 2006 WL 1540324, at *4 (N.Y. Sup. May 10, 2006)). As most New York courts have held: "[I]f the [complaint] alleges only a breach of an implied duty of good faith and fair dealing, and not a breach of contract, that cause of action must be dismissed." *Designers N. Carpet, Inc. v. Mohawk Indus., Inc.*, 153 F. Supp. 2d 193, 197 (E.D.N.Y. 2001).

New York appellate and trial courts thus routinely dismiss claims based on this implied covenant where, as here, no separate claim for breach of contract exists. For example, in *Triton Partners LLC v. Prudential Sec. Inc.*, 301 A.D.2d 411 (1st Dep't 2003), the intermediate appellate court in Manhattan affirmed the dismissal of an implied covenant claim because "it was merely a substitute for a nonviable breach of contract claim." *Id.* at 411. Similarly, in *Mandarin Trading Ltd. v. Wildenstein*, No. 602648/06, 2007 WL 3101235 (N.Y. Sup. Sept. 4, 2007), a Manhattan trial court held that the plaintiff's breach of the implied good faith and fair dealing claim "*must* . . . be dismissed" in the absence of a viable breach of contract claim. *Id.* at *7 (emphasis added).[1]

Notwithstanding this general rule and practice, some courts have held that a claim for breach of the implied covenant of good faith and fair dealing can stand alone in very limited circumstances. For example, an independent implied covenant claim may exist where a contracting party "exercised a [contract] right malevolently, for its own gain as part of a purposeful scheme designed to deprive plaintiffs of the benefits of [the bargain]." *Richbell Info. Servs., Inc. v. Jupiter Partners, L.P.*, 309 A.D.2d 288, 302 (1st Dep't 2003). The rationale for these holdings is that "[w]here the contract

[1] These cases are hardly alone. *See, e.g.*, *Nikitovich v. O'Neal*, 40 A.D.3d 300, 301 (1st Dep't 2007) ("A claim for breach of the implied covenant of fair dealing cannot substitute for an unsustainable breach of contract claim."); *Jacobs Private Equity, LLC v. 450 Park LLC*, 22 A.D.3d 347, 347-48 (1st Dep't 2005) (affirming dismissal of good faith and fair dealing claim as duplicative of non-viable breach of contract claim); *Cerberus Int'l Ltd. v. BancTec, Inc.*, 16 A.D.3d 126, 127 (1st Dep't 2005) (same); *Parker E. 67th Assocs., L.P. v. Minister, Elders & Deacons of the Reform Dutch Protestant Church of the City of New York*, 301 A.D.2d 453, 453 (1st Dep't 2003) (same); *Engelhard Corp. v. Research Corp.*, 268 A.D.2d 358, 358-59 (1st Dep't 2000) (same); *Cohen*, 2006 WL 1540324, at *4 (dismissing good faith and fair dealing claim).

contemplates the exercise of discretion, this pledge [*i.e.*, the implied covenant of good faith and fair dealing] includes a promise not to act arbitrarily or irrationally in exercising that discretion." *Dalton*, 87 N.Y.2d at 389.

This exception to the general prohibition against independent implied covenant claims does not apply here. The exception turns on the presence of a specific contractual provision giving one party discretion on a particular issue, where some courts have reasoned that a malicious abuse of that discretion may support an independent implied covenant claim. *See id.* But, here, there is nothing in the License Agreement remotely referencing Norvir's price, which is simply not a matter two competitors in the market for HIV drugs could agree upon without engaging in a per se violation of the Sherman Act.

GSK merely alleges that Abbott's "price increase [for Norvir] was illegitimate, arbitrary, capricious and done in bad faith." (Compl. ¶ 64). But it makes no effort to tie that allegation to any of the terms of the License Agreement, which creates no rights or obligations concerning Abbott's pricing decisions. Noticeably absent from Count 2, therefore, is any allegation that Abbott exercised *any* contractual right, let alone a discretionary right, in bad faith. As a result, this claim should suffer the same fate as the scores of similar misguided attempts to circumvent nonviable contract claims — dismissal.

**2. GSK Also Cannot Read New And Conflicting Implied Obligations Into The Parties' Express Contract**

Even if GSK could bring an implied covenant claim in the absence of a breach of contract (which it cannot), this claim still fails. New York law makes it clear that "[t]he covenant of good faith and fair dealing cannot be construed so broadly as to effectively nullify other express terms of the contract, or to create independent contractual rights." *Nat'l Union Fire Ins. Co. of Pittsburgh, PA v. Xerox Corp.*, 25 A.D.3d 309, 310 (1st Dep't 2006); *see also Sutton Assocs. v. Lexis-Nexis*, 761 N.Y.S.2d 800, 804 (N.Y. Sup. 2003) (holding that implied covenant of good faith and fair dealing "cannot be used to create independent obligations beyond those agreed upon and stated in the express language of the contract").

GSK ignores this well-established precedent by asking the Court to consider its purported

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"reasonable expectations" at the time of the contract to create new and conflicting contractual obligations, such as an obligation on the part of Abbott to make future Norvir price increases "consistent with past increases." (Compl. ¶ 64). Any such implied agreement directly contradicts the contractual provisions disclaiming any warranties beyond those expressly noted in the agreement and confirming that the agreement reflects "the *entire understanding of the parties* with respect to the subject matter hereof." (Ex. A, License Agreement ¶¶ 5.4, 11.5 (emphasis added)). New York law thus prohibits GSK from claiming that Abbott implicitly warranted or agreed not to increase the price of Norvir beyond some unspecified level. *See, e.g., Silvester v. Time Warner, Inc.*, 1 Misc. 3d 250, 258 (N.Y. Sup. 2003) (dismissing implied covenant claim because a party cannot rely on this doctrine to "impose any obligation upon a party to the contract beyond what the explicit terms of the contract provide").

Even putting aside this additional legal deficiency in Count 2, GSK's allegation that it "reasonably expect[ed]" the parties to agree on price limits for Norvir is absurd, which, by itself, is a grounds for dismissal given *Twombley*'s mandate that only "plausible" claims survive Rule 12(b)(6). *See also In re AST Research. Sec. Litig.*, 887 F. Supp. 231, 235 (C.D. Cal. 1995) (dismissing claim after finding "allegations are nonsensical"). There is no basis for this Court to find that GSK's purported expectation that the parties agreed to an illegal price-fixing agreement was "reasonable." Nor could this Court plausibly find that GSK reasonably expected Abbott to forfeit its right to set the price of its own product in whatever way it saw fit merely because Abbott granted GSK a license to combine two drugs. This is especially true given that the License Agreement is completely silent when it comes to pricing. GSK cannot construe the contract to mean something other than what it says. As a result, this Court should dismiss Count 2 and hold GSK to the express terms of the License Agreement.

### C. GSK Has Failed To State A Claim Under The North Carolina Unfair Trade Practices Act

GSK next invokes North Carolina law when it alleges a violation of North Carolina's Unfair Trade Practices Act in Count 3. In its effort to plead an "unfair and deceptive practice[]" under North Carolina law, GSK alleges that Abbott's actions "(1) violate antitrust laws, (2) constitute

inequitable assertions of Abbott's power or position, (3) violate the requirement that parties at all levels of commerce act in good faith and engage in fair dealings . . . , and (4) constitute deceptive acts." (Compl. ¶ 69). None of these allegations is sufficient to support this claim.

**1. North Carolina Has Not Adopted, And Would Not Adopt, GSK's Patent-Monopoly Leveraging Theory Of Antitrust Liability**

GSK relies primarily on its Sherman Act allegations to support Count 3 when alleging that Abbott's pricing decisions concerning Norvir "violate antitrust laws" and, along these same lines, constitute "inequitable assertions of Abbott's power or position" in violation of the North Carolina Unfair Trade Practices Act. (*Id*. at ¶ 69). The two statutes prohibit similar conduct. In fact, the Unfair Trade Practices Act was modeled after the Sherman Act and is "a comprehensive law designed to include within its reach the federal antitrust laws." *L.C. Williams Oil Co., v. Exxon Corp.*, 625 F. Supp. 477, 481 (M.D.N.C. 1985); *see also DKH Corp. v. Rankin-Patterson Oil Co.*, 506 S.E.2d 256, 258 (N.C. App. 1998). As a result, a finding by this Court that Abbott's conduct does not violate the Sherman Act would preclude GSK from showing an antitrust violation under North Carolina law. *See R.J. Reynolds Tobacco Co. v. Phillip Morris, Inc.*, 199 F. Supp. 2d 362, 395-96 (M.D.N.C. 2002).

Even if this Court were to conclude that GSK has stated a Sherman Act claim under Ninth Circuit precedent, GSK's allegations underlying its patent-monopoly leveraging theory still would not state a claim under the North Carolina Unfair Trade Practices Act. North Carolina law, not Ninth Circuit law, applies when determining whether Abbott's conduct violates the Unfair Trade Practices Act. Where, as here, there is no North Carolina Supreme Court decision construing whether the alleged conduct constitutes an antitrust violation, this Court must "predict how the state high court would resolve" the issue. *Westlands Water Dist. v. Amoco Chem. Co.*, 953 F.2d 1109, 1111 (9th Cir. 1991) (quotation omitted). North Carolina state courts, as well as federal courts applying North Carolina law, have held that federal decisions, while not binding, provide guidance in determining the scope and meaning of the Unfair Trade Practices Act.[2]

[2] *See, e.g., ITCO Corp. v. Michelin Tire Corp., Commercial Div.*, 722 F.2d 42, 48 (4th Cir. 1983); *Sewell Plastics, Inc. v. Coca-Cola Co.*, 720 F. Supp. 1196, 1221 (W.D.N.C 1989); *The In Porters, S.A. v. Hanes Printables, Inc.*, 663 F. Supp. 494, 501 (M.D.N.C. 1987); *Marshall v. Miller*,

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Although the North Carolina Supreme Court has yet to address the viability of a monopoly leveraging theory of antitrust liability, a federal district court in North Carolina has squarely rejected that theory. In *Bepco, Inc. v. Allied-Signal, Inc.*, 106 F. Supp. 2d 814 (M.D.N.C. 2000), the court explained this theory — the precise theory underlying GSK's complaint—as follows: "Under monopoly leveraging, a defendant who enjoys monopoly power in one market faces liability under Section 2 [of the Sherman Act] if it uses such monopoly power to gain unfair advantage in a second market, causing antitrust injury in the second market." *Id.* at 833. After examining several cases that have rejected this theory, the court did not believe "that the Fourth Circuit would recognize monopoly leveraging as a theory independent of attempted monopolization" and dismissed the claim. *Id.* We are aware of no decision by any North Carolina court—or, for that matter, any court in the Fourth Circuit—holding that such a theory of antitrust liability is viable. *See also See In re Microsoft Corp. Antitrust Litig.*, 333 F.3d 517, 532 (4th Cir. 2003) ("[T]he monopoly leveraging theory on which the district court relied has not been recognized in this circuit nor has it received general acceptance.").

Accordingly, this Court should find that North Carolina would chose to follow the majority rule as reflected in the Federal Circuit's holding that "the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws." *In re Indep. Servs. Orgs. Antitrust Litig.*, 203 F.3d at 1327. The Seventh Circuit (Judge Easterbrook) in *Schor v. Abbott Laboratories.*, 457 F.3d 608 (7th Cir. 2006), followed this reasoning and rejected identical claims against Abbott, holding that there is no "free-standing theory of 'monopoly leveraging,'" as alleged by GSK. *Id.* at 611, 613.

There is no basis to conclude that the North Carolina Supreme Court would look past these courts to the Ninth Circuit's decision in *Image Technical Services v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997), upon which GSK's theory of antitrust liability presumably is based. That decision stands alone in holding that the patent laws merely create a rebuttable presumption that the exercise of the statutory right to exclude provides a valid business justification for consumer harm. No court has followed this holding, and both the Federal and Seventh Circuits have expressly

276 S.E.2d 397, 403 (N.C. 1981) (citing *Johnson v. Phoenix Mut. Life Ins. Co.*, 266 S.E.2d 610, 620 (1980)).

rejected it. *See In re Indep. Servs. Orgs. Antitrust Litig.*, 203 F.3d at 1327 ("We decline to follow *Image Technical Services*."); *Schor*, 457 F.3d at 613 (finding that the Ninth Circuit "just got it wrong").[3] GSK thus has not adequately pleaded an antitrust violation sufficient to sustain its claim under the North Carolina Unfair Trade Practices Act.

**2. GSK's Allegations Of Bad Faith In Count 3 Are Misplaced Because Intent Is Irrelevant To A North Carolina Unfair Trade Practices Act Claim**

As an alternative basis to support its claim under the North Carolina Unfair Trade Practices Act, GSK alleges that Abbott's conduct "violate[s] the requirement that parties at all levels of commerce act in good faith and engage in fair dealings." (Compl. ¶ 69). This allegation confuses the statutory claim pleaded in Count 3 with the implied covenant of good faith and fair dealing claim in Count 2. The North Carolina Supreme Court has held that the intent of the actor is irrelevant to whether there has been a Unfair Trade Practices Act violation. *Marshall v. Miller*, 276 S.E.2d 397, 403 (N.C. 1981). Instead, "unfairness and deception are gauged by consideration of the effect of the practice on the marketplace." *Id*. Accordingly, GSK's allegation of bad faith in Count 3 should be summarily ignored as inapposite. *Id.*

**3. GSK Has Not Adequately Alleged Deceptive Conduct In Violation Of The North Carolina Unfair Trade Practices Act**

GSK also includes a catch-all allegation of "deceptive conduct" as part of a final effort to support its claim under the North Carolina Unfair Trade Practices Act. That allegation fails too because GSK failed to plead detrimental reliance. North Carolina law is clear that a claim based on deceptive acts cannot stand unless the "plaintiff can show that plaintiff detrimentally relied upon a statement or misrepresentation and he or she suffered actual injury as a proximate result." *Bus. Cabling, Inc. v. Yokeley*, 643 S.E.2d 63, 69 (N.C. App. 2007); *see also Coker v. DaimlerChrysler Corp.*, 617 S.E.2d 306, 316 (N.C. App. 2005).

[3] Other courts have similarly rejected monopoly leveraging theories. *See, e.g., Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415 n.4 (2004) (holding that complaint did not state a claim under a "monopoly leveraging" theory); *Virgin Atl. Airways, Ltd. v. British Airways PLC*, 257 F.3d 256, 272 (2d Cir. 2001) ("[U]ncertainty exists as to the continued scope of a monopoly leveraging claim as an independent cause of action in light of the Supreme Court's opinion in Spectrum Sports.") (citing *Sports, Inc. v. McQuillan*, 506 U.S. 447 (1993)); Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 652(b)(2) at 93 (1996) (observing that most circuits and district courts "reject most leveraging claims").

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GSK's allegations come nowhere close to satisfying this pleading requirement. GSK merely alleges that "Abbott deliberately deceived its competitors and the public as to the true and illegitimate nature of the price increase. . . . Abbott further misrepresented the pricing of Norvir to the public[.]" (Compl. ¶ 71). GSK has failed to allege that it detrimentally relied in any way on any of Abbott's purported misrepresentations. Nor does it allege any proximate injury resulting from the alleged deception. Accordingly, GSK's catch-all deception allegations do not save its deficient Unfair Trade Practices Act claim. *See Bus. Cabling, Inc.*, 643 S.E.2d at 69 (reversing the trial court's decision for plaintiff under North Carolina's Unfair Trade Practices Act because "the trial court failed to find as fact, and no evidence shows, plaintiff 'detrimentally relied upon'" the defendant's statement).

### D. GSK Has Failed To State A Claim Under The North Carolina Prohibition Against Monopolization

GSK's failure to state an antitrust claim under the North Carolina Unfair Trade Practices Act necessarily dooms Count 4, which alleges that Abbott violated the North Carolina prohibition against monopolization, N.C. Gen. Stat. § 75-2.1. In *R.J. Reynolds Tobacco Co. v. Phillip Morris, Inc.*, 199 F. Supp. 2d 362 (M.D.N.C. 2002), for example, a North Carolina federal district court dismissed such a claim because, like here, the plaintiffs failed to allege an antitrust violation in violation of federal law or North Carolina's Unfair Trade Practices Act. *Id*. at 395-96. It held that because the plaintiffs did "not allege any facts that suggest that Defendant's conduct is unlawful beyond the conduct that is the basis for their failed federal claims, Plaintiffs' state . . . statutory claims fail as well." *Id*. The same result is warranted here.

## V. CONCLUSION

For the reasons set forth above, this Court should dismiss all claims in GSK's complaint with prejudice.

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